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TITLE OF THE INVENTION

PORTABLE HAND PUMP FOR EVACUATION OF FLUIDS

This application claims priority from U.S. Provisional Application Serial No. 60/523,321 filed November 20, 2003. The entirety of that provisional application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to pumps for removing fluids from a body cavity of a subject. More particularly, the invention relates to a manually operated pump that can be used to remove fluids from a subject suffering from hemopneumothorax.

Background of the Technology

Penetrating chest injuries have been a major cause of death on the battlefield.[1] Injured soldiers with hemopneumothorax need treatment as soon as possible. The possibility of rapidly moving front lines and urban environment

combat may preclude rapid transportation of wounded soldiers to higher echelons of medical care.[2,3,4] The conventionally used equipment for the evacuation of blood and air from the pleural space of a subject is a large-bore thoracostomy tube connected to negative-pressure water seal devices, for example Pleur-Evac® (Deknatel Division of Pfizer, Corp.). Such currently available drainage systems are cumbersome, bulky, and difficult to manage during transport of the wounded soldier. Furthermore, continuous suction for the drainage system is seldom available under field conditions. Historically penetrating chest injuries resulting in pneumothorax[5] have been common. Such conditions have fortunately seen some decreases due to the use of body armor by soldiers[6]. Emergency treatment of such traumatic chest injuries does, however remain a major medical problem. Although one-way valves such as the Heimlich valves can be used and have been shown to be effective for simple pneumothroax[7,8,9,10], one distinct disadvantage is that by design such valves rely on gravity or increased intrathoracic pressure for drainage and do not provide suction to facilitate the evacuation of blood/clots and the re-expansion of the injured lung.

There exists therefore a need for a manually operated pump that can provide effective suction to remove fluids from a subject and more particularly to facilitate the effective treatment of traumatic hemopneumothorax in patients in an emergency/field environment where continuous suction is not available or easily employed.

SUMMARY OF THE INVENTION

The present invention provides a manually operable pump that can be quickly and easily employed under emergency or field conditions to remove fluids from a subject.

Also provided is an effective manually operable pump that can be used to remove fluids in the treatment of a subject suffering from hemopneumothorax.

Also provided is an effective pumping device that can by intermittent manual actuation effectively remove blood, blood clots, fluid, and air from a body cavity.

Also provided is a manually operable pump that is adapted for attachment to an intake fluid conduit and an outlet fluid conduit to facilitate the removal of fluid from a subject.

Also provided is a manually operable pump that is adapted for attachment and use with a range of conduits such as a standard pleural tube, a standard endotracheal tube, and an indwelling catheter for the effective removal of fluids and/or blood clots and air from the body cavity of a subject.

Also provided is a manually operable pump having one-way valves that serve to direct the movement of fluid in only one direction when the pump is manually activated.

Also provided is a manually operable pump for the removal of fluids from a body cavity of a subject, the manual operation being accomplished by contact with any limb or body part of the operator.

Also provided is a manually operable pump that is configured to be selectively connected to an autotransfusion device.

Also provided is a manually operable pump having one-way valves of such sensitivity that the valves can effectively direct the movement of fluid in only one direction without manual activation and with the aid of gravity flow alone.

Also provided is a manually operable pump that effectively removes blood, blood clots, fluid, and air from a body cavity without the aid of wall suction, rigid containers, water-seal devices, or electricity.

Also provided is a system of manually operable pumps, which can be connected as multiple successive pumps to effectively remove blood, blood clots, fluid, and air from a body cavity.

Also provided is a manually operable pump that effectively removes blood, blood clots, fluid, and air from a body cavity, the pump generating a negative pressure in the range of 5 mm to 100 mm Hg.

BRIEF DESCRIPTION OF FIGURES

Figure 1 provides a planar view of a basic embodiment of the manually operable pump of the present invention.

Figure 2 shows the comparative experimental results of a conventional device employing the standard of care for treating hemopneumothorax as compared to the operational results obtained by use of the manually operable pump of the present invention employing a standard pleural tube in one case and the manually

operable pump of the present invention using a standard endotracheal tube in a second case.

DETAILED DESCRIPTION OF THE INVENTION

At present, manual suction devices are not available for use during the care and initial treatment of a subject in an emergency situation. Such a device would be particularly useful in providing emergency care for combat casualties, who frequently are in danger of serious injury or death due to traumatic hemopneumothorax. A manually operated pump that can evacuate blood or air from the throat, air passages, or chest would be most beneficial in the treatment of casualties who have suffered injuries to the chest. The pumping device of the present invention can also be adapted for other medical treatment uses such as, for example, checking correct placement of an endotracheal tube (tube placed in the wind pipe) and evacuating secretions from the nose, mouth, and air passages or to evacuate fluids out of drains that have been placed into various body cavities during surgery. The manufacture and design of the pump is such that it can be sterilized and repeatedly reused or it can be cost-effectively produced so as to be disposed of after only one use.

Currently, electrical or battery operated suction devices are available but due to the austere environment often faced by the military, having a suction device that does not have to rely on electricity or batteries would be of benefit, especially when transporting the patient. Such conventional devices typically use a water seal

as a one way valve and drainage is passive unless the system is connected to a suction source. The electrical suction devices available in the market are cumbersome and not suitable for use in the military environment and during transportation. Further, such devices can suddenly be of no use if the power supply to the conventional device is interrupted. Other one way valves are in existence but again they rely on gravity or increased pressure in the chest to help push out undesired air or fluids. The present invention provides a manually operable suction device that can pump large volumes of fluid (such as blood, water, mucus, blood clots, air, etc.) from a body cavity of a subject suffering from serious conditions brought on by chest injuries or other traumatic conditions where a manually operable pump would have potential life-saving benefit.

Unlike conventional devices and the standard of care currently provided for the removal of fluids from the body cavity of a subject, the present invention is not cumbersome, bulky, dependent on electrical powered wall suction or battery operated suction. Further it is small, simply configured and easy to transport under extreme, emergency, or combat conditions. Further, unlike the conventionally used Heimlich valves, which rely on gravity or increased intra-thoracic pressure for drainage, and do not provide suction to facilitate evacuation of blood/clots and re-expansion of the injured lung, the present invention can provide very effective removal of fluid, blood clots and air from the body cavity of a subject.

As shown in Figure 1, the small, portable, easy to use manual pump (10) of the present invention can be adapted for attachment to virtually any usable fluid conduit as an inflow conduit (12) or an outflow conduit (14). Importantly,

proximate to the connection of the inflow conduit (12), the pump of the present invention is provided with a one-way inflow valve (16) that acts to permit flow of fluids, blood clots, and air from the inflow conduit (12) into the interior of the pump (18) but limits or restricts any back flow of the same into the inflow conduit (12). Similarly, proximate to the connection of the outflow conduit (14), a one-way outflow valve (20) permits flow of fluids, blood clots, and air out of the pump interior (16) and into and through the lumen of the outflow conduit (14). This outflow one-way valve (20) also serves to limit or restrict the back flow of fluids from the outflow conduit into the pump interior (18). The one-way valves used in the present invention can be of any conventional configuration known for one-way flow valves and can be selected to be of such sensitivity that the pump device can be positioned so as to permit passage of fluid through the device by force of gravity alone if desired.

The pump (10) can be constructed of any material strong enough to withstand repeated manual compressions, flexible enough to facilitate easy manual use by the operator in compressing the body (22) of the pump, durable over prolonged and repeated usage, and fluid-tight so as to prohibit any leakage during use. The material used in the manufacture of the cylindrical bladder of the body (22) of the pump can be a natural, synthetic, or blended material suitable for the operational demands of the manually operable pump. The materials used in the manufacture of the pump can be of the nature to withstand sterilization and repeated uses or can be more cost-effectively manufactured for single use and disposal.

The manually operable pump of the present invention is very adaptable and is particularly well suited for connection to well known and commonly used thoracostomy tubes, endotracheal tubes or catheters, which are readily available to emergency medical practitioners or military field medics or corpsmen. This simple design, light weight transportability, and adaptability to many fluid conduits as needed offers a major logistical advantage in austere environments.

In addition to its usefulness to emergency military medical needs, the present invention offers additional logistical advantages of requiring no wall suction, rigid containers, water or electricity makes the present invention a very useful device for civilian applications, such as for civilian ground ambulance or medical helicopter transport emergency suction needs. Further, the device is also adaptable in that the outflow conduit can be connected to an auto-transfusion unit if needed. Indeed, any circumstance where a manually operable pump is needed could be met by the device of the present invention.

Example:

A test example of the device of the present invention was prepared by providing two pieces of clear vinyl tubing (4 inches in length and ½ inch inside diameter), which were connected to a cylindrical rubber bladder (1.5x3 inch) using adaptors and two one-way valves. The position of the one-way valves on both ends of the rubber bladder ensured that fluid could only move in one direction on squeezing the bladder (Figure 1). The inflow vinyl tubing was attached to the

pleural evacuation tube whereas the outflow tubing was attached to a collection bag for the measurement of evacuated blood.

A swine model of penetrating chest injury was designed to test the concept of the present invention. The purpose of the test was to compare the effectiveness of operation of the manually operable pump of the present invention to the conventional device and accepted standard of care for the evacuation of a large hemopneumothorax. The present invention pump was tested in a swine model of penetrating chest injury and bleeding in the pleural space. Table 1 provides the test data obtained for test groups 1, 2, and 3. Test Group 1, was a conventional standard of care model. Test Group 2 was the manually operable pump of the present invention connected to a conventionally used chest tube. Test Group 3, was designed to demonstrate the adaptability of the present invention in that the manually operable hand pump was connected to an endotracheal tube rather than the conventionally used chest tube. As can be seen in the data of Table 1, overall, the manually operable pump performed better than the standard of care and was also shown to be very effective when connected to a conventional chest tube or an endotracheal tube.

TABLE 1 Selected Hemodynamic and Physiologic Variables[a]

Variable	Groups	Time				
		Baseline	30 Min	60 Min	90 Min	120 Min
MAP (mm Hg)	1	77.33 ± 7.02	76.67 ± 6.96	54.67 ± 6.10	50.83 ± 3.96	51.00 ± 2.49
	2	79.67 ± 4.79	72.00 ± 4.91	63.00 ± 5.07	56.83 ± 6.26	50.67 ± 5.02
	3	80.33 ± 4.25	72.17 ± 6.38	64.83 ± 6.21	53.00 ± 7.27	51.50 ± 4.77
Ph	1	7.48 ± 0.02	7.44 ±0.01	7.42 ± 0.01	7.41 ± 0.02	7.42 ± 0.02
	2	7.44 ± 0.01	7.41 ± 0.02	7.36 ± 0.02	7.37 ± 0.02	7.41 ± 0.02
	3	7.43 ± 0.01	7.40 ± 0.01	7.39 ± 0.01	7.39 ± 0.02	7.38 ± 0.02
BE (mmol/L)	1	6.63 ± 1.53	4.98 ± 2.39	5.7 ± 1.09	6.45 ± 1.94	7.85 ± 1.08
	2	6.68 ± 2.87	8.38 ± 1.55	6.7 ± 1.14	9.64 ± 1.25	7.78 ± 1.71
	3	5.91 ± 1.52	8.38 ± 1.24	6.92 ± 1.14	6.78 ± 0.87	5.62 ± 1.92
CO (L/min)	1	4.09 ± 0.35	4.78 ± 0.60	4.72 ± 0.46	3.91 ± 0.37	3.12 ± 0.17
	2	4.09 ± 0.38	4.26 ± 1.31	5.26 ± 0.61	4.37 ± 0.94	3.51 ± 0.31
	3	4.27 ± 0.42	5.62 ± 1.31	5.77 ± 1.18	4.42 ± 0.99	4.41 ± 1.26
Hg (g/dL)	1	9.03 ± 0.054	8.88 ± 0.74	7.18 ± 0.36	7.80 ± 0.43	8.75 ± 0.35
	2	8.37 ± 0.050	7.68 ± 0.34	6.36 ± 0.60	7.83 ± 0.71	7.52 ± 0.48
	3	8.93 ± 0.60	8.13 ± 0.59	6.74 ± 0.46	7.62 ± 0.70	7.98 ± 0.41
Lactate (mmol/L)	1	0.65 ± 0.13	0.72 ± 0.10	0.75 ± 0.13	0.60 ± 0.10	0.77 ± 0.09
	2	0.97 ± 0.31	0.70 ± 0.11	0.52 ± 0.08	0.67 ± 0.20	1.02 ± 0.20
	3	0.78 ± 0.07	1.32 ± 0.20	0.92 ± 0.16	1.05 ± 0.26	1.23 ± 0.30

MAP, mean arterial pressure; BE, base excess; Hg, hemoglobin B.

[a]Data are presented as group means ± SEM. Group 1, Standard of care: a 36-F Argyle chest tube connected to Pleu-Evac chest drainage unit; Group 2, 36-F Argyle chest tube connected to the manually operable pump; Group 3, 8.0-mm endotracheal tube connected to the manually operable pump. Baseline = before hemorrhage and placement of pleural evacuation device; time = minutes from initiation of hemorrhage.

The results of the comparative tests are summarized and graphically displayed in Figure 2. In addition, it was found that the device of the present invention was able to pump water at a maximum rate of 1L/minute. The negative

pressure generated in the pleural tube (in vivo) was affected by the rate of pumping.

Notably, a single pump generated negative pressure of 12mmHg and it was found that multiple successive pumps could generate a maximum pressure of -80-90 mmHg.

The present invention can be manually operate by compression of the pump body (22) by any manual means; that is, it is within the concept of the invention that the pump can be sized and configured to be pump by hand compression using only one hand, it can be configured slightly larger to be compressed by an operator with both hands, it can also be sized, shaped, and even externally textured to avoid slippage and made compressible by foot or pedal activation. Any body part can be used to compress the body (22) of the present invention and remain within the concept of the present invention. Further, any shape, construction, material, or size of conduit for the inflow and outflow conduits can be used within the concept of the present invention.

The adaptability of the present invention permits that the device can be so positioned as to permit fluid transport through the one-way valves and through the pump by use of gravity powered flow alone. It is also within the concept of the invention that the manually operable pump can be configured to be selectively connected to an autotransfusion device. Further, it is possible in the present invention to attach suction handles to suck out secretions from the mouth, checking for correct tube placement when a tube must be properly positioned in the

windpipe, and to suck fluids out of drains, catheters, or other conduits, which have been placed surgically.

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